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In re Application of :
Yunik Chang, et al :
Application No. 07/326,536 : LETTER
Filed: March 21, 1989 :
Attorney Docket No. 29065000320 :

This is in response to the paper filed June 7, 1999 under 37 CFR 1.28 (b) requesting that status as a Small Entity be removed.

In accordance with the June 7, 1999 request, status as a Small Entity has been removed.

The file is being forwarded to the Files Repository.

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HF® with a mixture consisting of 50%/39%/10%/1% (volume percent) ethanol/water/glycerine/glycerol monooleate to provide a gel with a final pindolol concentration of 65 mg/cc and Klucel level of 1.5% (wt/wt).

The pindolol-enhancer gel is pipetted (0.4 ml) onto the L1 laminate and a Scotchpak 1012 backing film (0.4 ml cup previously formed) is positioned over the laminate. The backing film is then heat sealed to the L1 laminate and a final system is die cut as described in Example 1. When the release liner is peeled from the system, the peel force between the adhesive and release liner is greater than the force necessary to break the peelable seal between the peelable disc and the microporous membrane. The peelable disc is thus removed from the system with the release liner, creating the peripheral adhesive and exposing the drug-enhancer delivery surface area. The in vitro pindolol skin flux from the system is determined using the methods of Merritt and Cooper, supra, to be 33 ug/cm^2/hr.

Example 3

An L1 laminate is prepared as described in Example 1 using a polyisobutylene (PIB) adhesive in place of the silicone adhesive and a Daubert C-150 release liner in place of the Akrosil Biorelease release liner. A nicardipine-enhancer gel formulation is prepared by mixing adequate quantities of nicardipine HCl and Klucel HF® with a 65%/10%/20%/5% (volume percent) mixture of ethanol/water/glycerine/glycerol monooleate to provide a final gel with a nicardipine concentration of 150 mg/cc and a Klucel level of 1.5% (wt/wt). A nicardipine transdermal system is then prepared as described in Example 1 using the nicardipine-enhancer gel formulation.

As with the previous examples, the peel force between the PIB adhesive and the release liner is greater than the force necessary to break the peelable seal